Agency for Healthcare Research and Quality
Advancing Excellence in Health Care

NATIONAL GUIDELINE CLEARINGHOUSE

General

Guideline Title

Surgical treatment of female stress urinary incontinence: AUA/SUFU guideline.

Bibliographic Source(s)

Kobashi KC, Albo ME, Dmochowski RR, Ginsberg DA, Goldman HB, Gomelsky A, Kraus SR, Sandhu JS, Shepler T, Treadwell JR, Vasavada S, Lemack GE. Surgical treatment of female stress urinary incontinence: AUA/SUFU guideline. Linthicum (MD): American Urological Association Education and Research, Inc.; 2017 Mar. 33 p. [87 references]

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: American Urological Association Education and Research. Guideline for the surgical management of female stress urinary incontinence: 2009 update. Linthicum (MD): American Urological Association Education and Research, Inc.; 2009. 44 p. [31 references]

This guideline meets NGC's 2013 (revised) inclusion criteria.

NEATS Assessment

National Guideline Clearinghouse (NGC) has assessed this guideline's adherence to standards of trustworthiness, derived from the Institute of Medicine's report Clinical Practice Guidelines We Can Trust.

= Poor = Fair = Good = Very Good = Excellent

Assessment	Standard of Trustworthiness
YES	Disclosure of Guideline Funding Source
	Disclosure and Management of Financial Conflict of Interests

	Guideline Development Group Composition
YES	Multidisciplinary Group
YES	Methodologist Involvement
▮▮▮▯▯	Patient and Public Perspectives
	Use of a Systematic Review of Evidence
▮▮▮▮▮	Search Strategy
▮▮▮▮▮	Study Selection
▮▮▮▮▮	Synthesis of Evidence
	Evidence Foundations for and Rating Strength of Recommendations
▮▮▮▮▮	Grading the Quality or Strength of Evidence
▮▮▮▮▮	Benefits and Harms of Recommendations
▮▮▮▮▮	Evidence Summary Supporting Recommendations
▮▮▮▮▮	Rating the Strength of Recommendations
▮▮▮▮▮	Specific and Unambiguous Articulation of Recommendations
▮▮▮▮▯	External Review
▮▮▮▮▮	Updating

Recommendations

Major Recommendations

Definitions for the body of evidence strength (Grade A, B, or C), the strength of the recommendations (Strong, Moderate, Conditional), and for statements labeled as Clinical Principle and Expert Opinion are provided at the end of the "Major Recommendations" field.

Patient Evaluation

In the initial evaluation of patients with stress urinary incontinence desiring to undergo surgical intervention, physicians should include the following components: (Clinical Principle)

- History, including assessment of bother
- Physical examination, including a pelvic examination
- Objective demonstration of stress urinary incontinence with a comfortably full bladder (any method)
- Assessment of post-void residual urine (any method)
- Urinalysis

Physicians should perform additional evaluations in patients being considered for surgical intervention who have the following conditions: (Expert Opinion)

- Inability to make definitive diagnosis based on symptoms and initial evaluation
- Inability to demonstrate stress urinary incontinence
- Known or suspected neurogenic lower urinary tract dysfunction
- Abnormal urinalysis, such as unexplained hematuria or pyuria
- Urgency-predominant mixed urinary incontinence
- Elevated post-void residual per clinician judgment
- High grade pelvic organ prolapse (POP-Q stage 3 or higher) if stress urinary incontinence not demonstrated with pelvic organ prolapse reduction
- Evidence of significant voiding dysfunction

Physicians may perform additional evaluations in patients with the following conditions: (Expert Opinion)

- Concomitant overactive bladder symptoms
- Failure of prior anti-incontinence surgery
- Prior pelvic prolapse surgery

Cystoscopy and Urodynamic Testing

Physicians should not perform cystoscopy in index patients for the evaluation of stress urinary incontinence unless there is a concern for urinary tract abnormalities. (Clinical Principle)

Physicians may omit urodynamic testing for the index patient desiring treatment when stress urinary incontinence is clearly demonstrated. (Conditional Recommendation; Evidence Level: Grade B)

Physicians may perform urodynamic testing in non-index patients. (Expert Opinion)

Patient Counseling

In patients wishing to undergo treatment for stress urinary incontinence, the degree of bother that their symptoms are causing them should be considered in their decision for therapy. (Expert Opinion)

In patients with stress urinary incontinence or stress-predominant mixed urinary incontinence who wish to undergo treatment, physicians should counsel regarding the availability of the following treatment options: (Clinical Principle)

- Observation
- Pelvic floor muscle training (± biofeedback)
- Other non-surgical options (e.g., continence pessary)
- Surgical intervention

Physicians should counsel patients on potential complications specific to the treatment options. (Clinical Principle)

Prior to selecting midurethral synthetic sling procedures for the surgical treatment of stress urinary incontinence in women, physicians must discuss the specific risks and benefits of mesh as well as the alternatives to a mesh sling. (Clinical Principle)

Treatment

In patients with stress urinary incontinence or stress-predominant mixed urinary incontinence, physicians may offer the following non-surgical treatment options: (Expert Opinion)

- Continence pessary
- Vaginal inserts
- Pelvic floor muscle exercises

In index patients considering surgery for stress urinary incontinence, physicians may offer the following options: (Strong Recommendation; Evidence Level: Grade A)

- Midurethral sling (synthetic)
- Autologous fascia pubovaginal sling
- Burch colposuspension
- Bulking agents

In index patients who select midurethral sling surgery, physicians may offer either the retropubic or transobturator midurethral sling. (Moderate Recommendation; Evidence Level: Grade A)

Physicians may offer single-incision slings to index patients undergoing midurethral sling surgery

with the patient informed as to the immaturity of evidence regarding their efficacy and safety. (Conditional Recommendation; Evidence Level: Grade B)

Physicians should not place a mesh sling if the urethra is inadvertently injured at the time of planned midurethral sling procedure. (Clinical Principle)

Physicians should not offer stem cell therapy for stress incontinent patients outside of investigative protocols. (Expert Opinion)

Special Cases

In patients with stress urinary incontinence and a fixed, immobile urethra (often referred to as 'intrinsic sphincter deficiency') who wish to undergo treatment, physicians should offer pubovaginal slings, retropubic midurethral slings, or urethral bulking agents. (Expert Opinion)

Physicians should not utilize a synthetic midurethral sling in patients undergoing concomitant urethral diverticulectomy, repair of urethrovaginal fistula, or urethral mesh excision and stress incontinence surgery. (Clinical Principle)

Physicians should strongly consider avoiding the use of mesh in patients undergoing stress incontinence surgery who are at risk for poor wound healing (e.g., following radiation therapy, presence of significant scarring, poor tissue quality). (Expert Opinion)

In patients undergoing concomitant surgery for pelvic prolapse repair and stress urinary incontinence, physicians may perform any of the incontinence procedures (e.g., midurethral sling, pubovaginal sling, Burch colposuspension). (Conditional Recommendation; Evidence Level: Grade C)

Physicians may offer patients with stress urinary incontinence and concomitant neurologic disease affecting lower urinary tract function (neurogenic bladder) surgical treatment of stress urinary incontinence after appropriate evaluation and counseling have been performed. (Expert Opinion)

Physicians may offer synthetic midurethral slings, in addition to other sling types, to the following patient populations after appropriate evaluation and counseling have been performed: (Expert Opinion)

- Patients planning to bear children
- Diabetes
- Obesity
- Geriatric

Outcomes Assessment

Physicians or their designees should communicate with patients within the early postoperative period to assess if patients are having any significant voiding problems, pain, or other unanticipated events. If patients are experiencing any of these outcomes, they should be seen and examined. (Expert Opinion)

Patients should be seen and examined by their physicians or designees within six months post-operatively. Patients with unfavorable outcomes may require additional follow-up. (Expert Opinion)

- The subjective outcome of surgery as perceived by the patient should be assessed and documented.
- Patients should be asked about residual incontinence, ease of voiding/force of stream, recent urinary tract infection, pain, sexual function and new onset or worsened overactive bladder symptoms.
- A physical exam, including an examination of all surgical incision sites, should be performed to evaluate healing, tenderness, mesh extrusion (in the case of synthetic slings), and any other potential abnormalities.
- A post-void residual should be obtained.
- A standardized questionnaire (e.g., Patient Global Impression of Improvement [PGI-I]) may be considered.

Definitions

Body of Evidence Strength

Grade A: Well-conducted and highly-generalizable randomized controlled trials (RCTs) or exceptionally

strong observational studies with consistent findings

Grade B: RCTs with some weaknesses of procedure or generalizability or moderately strong observational studies with consistent findings

Grade C: RCTs with serious deficiencies of procedure or generalizability or extremely small sample sizes or observational studies that are inconsistent, have small sample sizes, or have other problems that potentially confound interpretation of data

Note: By definition, Grade A evidence is evidence about which the Panel has a high level of certainty, Grade B evidence is evidence about which the Panel has a moderate level of certainty, and Grade C evidence is evidence about which the Panel has a low level of certainty.

American Urological Association (AUA) Nomenclature Linking Statement Type to Level of Certainty, Magnitude of Benefit or Risk/Burden, and Body of Evidence Strength

	Evidence Strength A (High Certainty)	**Evidence Strength B (Moderate Certainty)**	**Evidence Strength C (Low Certainty)**
Strong Recommendation (Net benefit or harm substantial)	Benefits > Risks/Burdens (or vice versa) Net benefit (or net harm) is substantial Applies to most patients in most circumstances and future research is unlikely to change confidence	Benefits > Risks/Burdens (or vice versa) Net benefit (or net harm) is substantial Applies to most patients in most circumstances but better evidence could change confidence	Benefits > Risks/Burdens (or vice versa) Net benefit (or net harm) is substantial Applies to most patients in most circumstances but better evidence is likely to change confidence (rarely used to support a Strong Recommendation)
Moderate Recommendation (Net benefit or harm moderate)	Benefits > Risks/Burdens (or vice versa) Net benefit (or net harm) is moderate Applies to most patients in most circumstances and future research is unlikely to change confidence	Benefits > Risks/Burdens (or vice versa) Net benefit (or net harm) is moderate Applies to most patients in most circumstances and future research is unlikely to change confidence	Benefits > Risks/Burdens (or vice versa) Net benefit (or net harm) appears moderate Applies to most patients in most circumstances and future research is unlikely to change confidence
Conditional Recommendation (No apparent net benefit or harm)	Benefits = Risks/Burdens Best action depends on individual patient circumstances Future research unlikely to change confidence	Benefits = Risks/Burdens Best action depends on individual patient circumstances Better evidence could change confidence	Balance between Benefits & Risks/Burdens unclear Alternative strategies may be equally reasonable Better evidence likely to change confidence
Clinical Principle	A statement about a component of clinical care that is widely agreed upon by urologists or other clinicians for which there may or may not be evidence in the medical literature		
Expert Opinion	A statement, achieved by consensus of the Panel, that is based on members' clinical training, experience, knowledge, and judgment for which there is no evidence		

Clinical Algorithm(s)

An algorithm titled "Female Stress Urinary Incontinence: AUA/SUFU Evaluation and Treatment Algorithm"

is available from the American Urological Association (AUA) Education and Research, Inc. Web site .

Scope

Disease/Condition(s)

Female stress urinary incontinence (SUI)

Guideline Category

Counseling

Diagnosis

Evaluation

Management

Treatment

Clinical Specialty

Obstetrics and Gynecology

Surgery

Urology

Intended Users

Physicians

Guideline Objective(s)

To outline the currently available treatment techniques for surgical management of female stress urinary incontinence as well as the data associated with each treatment

Target Population

- Otherwise healthy females who are considering surgical therapy for the correction of pure stress and/or stress-predominant mixed urinary incontinence (MUI) who have not undergone previous stress urinary incontinence (SUI) surgery, including patients with low-grade pelvic organ prolapse (index patients)
- Women with SUI and pelvic prolapse (stage 3 or 4), MUI (non-stress-predominant), incomplete emptying/elevated post-void residual (PVR) and/or other voiding dysfunction, prior surgical interventions for SUI, recurrent or persistent SUI, mesh complications, high body mass index (BMI), neurogenic lower urinary tract dysfunction and advanced age (geriatric) (non-index patients)

Interventions and Practices Considered

Diagnosis/Evaluation

- History and physical examination
- Objective demonstration of stress urinary incontinence (SUI)
- Post-void residual (PVR) assessment
- Urinalysis
- Urodynamics
- Cystoscopy (not to be performed unless there is a concern for lower urinary tract abnormalities)

Counseling/Treatment/Management

- Assessment of degree of bother of symptoms
- Counseling regarding nonsurgical options including
  - Pelvic floor training
  - Continence pessaries
  - Vaginal inserts
- Counseling regarding potential complications of all treatments
- Counseling on specific risks and benefits of mesh as well as the alternatives to a mesh sling
- Surgical options
  - Bulking agents
  - Midurethral sling (synthetic)
  - Autologous fascia pubovaginal sling
  - Burch colposuspension
- Considerations for special cases (fixed immobile urethra, concomitant surgery for pelvic organ prolapse repair, concomitant neurogenic urinary tract dysfunction, women planning to bear children, and diabetic, obese, or geriatric patients)
- Outcome assessment and follow-up

Major Outcomes Considered

- Quality of life (QoL)
- Questionnaires (assessment of symptoms, QoL, sexual function, satisfaction, expectation, bother)
- Voiding diaries
- Stress test
- Pad test
- Urodynamics
- Surgical complications/adverse events
- Need for retreatment
- Review of Urinary Incontinence Treatment Network (UITN) criteria
- Complications (e.g., erosion, extrusion, retention, voiding dysfunction, perforation, dyspareunia, obstruction, exposure, de novo urgency, recurrent urinary tract infection, bleeding, pain, neuropathy, neurovascular or visceral injury, hematoma, infection, hernia, seroma, slow stream)
- Rates of "success" or "failure" (generally based on a set of other variables such as stress tests, patient reports, and the need for retreatment)

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Systematic Review

A comprehensive search of the literature was performed by ECRI Institute. This search included articles published between January 1, 2005 and December 31, 2015. Study designs included systematic reviews, randomized controlled trials (RCTs), controlled clinical trials (CCTs), and observational studies (diagnostic accuracy studies, cohort with and without comparison group, case-control, case series). Three methodologic research analysts reviewed the abstracts identified in the literature search; each article was screened by at least two of the three analysts. Articles that potentially fulfilled the outlined inclusion criteria and potentially answered one or more of the questions specified by the panel were retrieved in full text for review by the team. For all excluded studies, analysts recorded the reason for exclusion as well as whether the exclusion was based on abstract review or full text review. To focus the analysis on the most relevant evidence, analysts only considered articles published in full after January 1, 2005 in the English language and that reported stress urinary incontinence (SUI) data for one or more of the Key Questions. An update abstract search was conducted through September 2016, which pulled in an additional 66 abstracts related to the key questions of interest.

Included Interventions

Included interventions were limited to those that were U.S. Food and Drug Administration (FDA)-approved with adequate robust data. Injectable bulking agents (Macroplastique, Coaptite, Contigen [collagen], silicone, Durasphere [carbon coated zirconium beads]); retropubic bladder neck suspensions (Burch colposuspension); midurethral slings (MUS) (retropubic [SPARC, TVT, ALIGN, Supris, Advantage, Lynx, Desara, I-STOP, TFS], transobturator [TVT-O, Monarc, ALIGN TO, Obtryx, Aris], Prepubic, Adjustable [Remeex]); pubovaginal slings (PVS) (autologous, allograft, xenograft); artificial urinary sphincter; single incision (Altis, MiniArc, Ajust, Solyx, SIMS, TVT-Secure).

Excluded Interventions

Laparoscopic colposuspension*, Obtape, ProteGen, Gore-Tex, bone-anchor, multifilament, In-Fast, anterior vaginal wall sling, Renessa, stem cell/tissue engineering, adjustable continence therapy, Bulkamid, MMK (Marshall-Marchetti-Krantz), needle suspensions (Stamey, Pereyra, Raz, Gittes), anterior colporrhaphy, Kelly plication.

*While the Panel acknowledges that a minimally invasive Burch colposuspension may be utilized by some individuals, neither laparoscopic nor robotic Burch colposuspension, specifically, were included due to the lack of sufficient data regarding these approaches in the literature.

Included Comparisons

Any comparisons of two or more of the included interventions was incorporated, though not all comparisons within a given category (e.g., comparisons of two bulking agents, or comparisons of two retropubic midurethral slings [RMUS]) were included. Additionally, analysts compared bottom-up versus top-down RMUS, as well as outside-in versus inside-out transobturator midurethral slings (TMUS).

Outcomes

The following outcomes are included in this review: Quality of life (QOL) questionnaires (symptom, QOL, sexual function, satisfaction, expectation, bother), voiding diaries, stress test, pad test, urodynamics, surgical complications/adverse events, need for retreatment, Urinary Incontinence Treatment Network (UITN)-based criteria, and complications (e.g., erosion, extrusion, retention, voiding dysfunction, perforation, dyspareunia, obstruction, exposure, de novo urgency, recurrent urinary tract infection [UTI], bleeding, pain, neuropathy, neurovascular or visceral injury, hematoma, infection, hernia, seroma, slow stream). Many studies reported rates of "success" or "failure," which was defined differently by different studies. Generally, outcomes were based on a set of variables such as stress tests, patient reports, and the need for retreatment.

Number of Source Documents

Of the 450 publications retrieved for full review, 256 were excluded. The most common reasons for exclusion were RCTs that were a part of already included systematic reviews to avoid duplication. A total of 194 publications were included.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Body of Evidence Strength

Grade A: Well-conducted and highly-generalizable randomized controlled trials (RCTs) or exceptionally strong observational studies with consistent findings

Grade B: RCTs with some weaknesses of procedure or generalizability or moderately strong observational studies with consistent findings

Grade C: RCTs with serious deficiencies of procedure or generalizability or extremely small sample sizes or observational studies that are inconsistent, have small sample sizes, or have other problems that potentially confound interpretation of data

Note: By definition, Grade A evidence is evidence about which the Panel has a high level of certainty, Grade B evidence is evidence about which the Panel has a moderate level of certainty, and Grade C evidence is evidence about which the Panel has a low level of certainty.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Data Extraction and Data Management

Information from each included article was extracted by one of three analysts using standard extraction forms. The team lead developed the forms and trained the extractors. The lead reviewed the work of the other extractors and searched for inconsistencies and missing information in the extracted data.

Assessment of Quality

Because different Key Questions involved different types of evidence, analysts tailored the quality assessments as follows:

> For systematic reviews, analysts rated quality based on the review authors' ratings of the quality of their included studies (if review authors did not rate quality, analysts extrapolated a rating based on their description of study limitations). For diagnostic cohort studies, analysts used the Quality Assessment of Diagnostic Accuracy Studies (QUADAS)-2 instrument.
> In reviewing effectiveness, analysts judged the quality of systematic reviews and randomized controlled trials (RCTs) using the same processes as previously discussed.
> For complications, analysts divided the evidence into comparative data (comprising systematic reviews and RCTs) and non-comparative data (comprising individual groups from RCTs and non-randomized studies).
> For comparative data, analysts used the same processes as previously discussed. For non-comparative data, analysts considered three items: prospective design, consecutive enrollment, and objective measurement of outcome. If all three were clearly true, the study was high quality; if just

one was false or unclear, the study was moderate quality. If two or three were false or unclear, the study was low quality.
In reviewing contraindications for midurethral slings (MUS) and indications for injectables, analysts did not assess quality because those questions involve patient enrollment criteria.
In reviewing preoperative cystoscopy, analysts identified no studies on the effect of preoperative cystoscopy, so no quality assessment was necessary.
For urodynamics, analysts judged the quality of randomized trials using the Cochrane risk-of-bias instrument.
For patient factors predicting outcomes, analysts used the Quality in Prognostic Studies (QUIPS) tool.
In reviewing outcomes instruments, analysts did not assess quality since it is not clear what would constitute a high quality study of instruments utilized to assess such outcomes.
In reviewing length of follow-up, analysts judged quality solely on the basis of the percentage of enrolled patients who provided data during follow-up. Studies for which all follow up time points had 85%+ completion were deemed high quality; studies for which any follow up time point had 60% or less completion were deemed low quality; all others were deemed moderate quality.

Determination of Evidence Strength

The categorization of evidence strength is conceptually distinct from the quality of individual studies. Evidence strength refers to the body of evidence available for a particular question and includes not only individual study quality but consideration of study design, consistency of findings across studies, adequacy of sample sizes, and generalizability of samples, settings, and treatments for the purposes of the guideline. See the "Rating Scheme for the Strength of the Evidence" field for the categories of the body of evidence.

Methods Used to Formulate the Recommendations

Expert Consensus

Expert Consensus (Delphi)

Description of Methods Used to Formulate the Recommendations

The Surgical Management of Female Stress Urinary Incontinence Panel was created in 2014 by the American Urological Association Education and Research, Inc. (AUA). The Practice Guidelines Committee (PGC) of the AUA selected the Panel Chair who in turn appointed the Vice Chair. In a collaborative process, additional Panel members, including additional members of the Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU) with specific expertise in this area, were then nominated and approved by the PGC.

AUA Nomenclature: Linking Statement Type to Evidence Strength

The AUA nomenclature system explicitly links statement type to body of evidence strength, level of certainty, magnitude of benefit or risk/burdens, and the Panel's judgment regarding the balance between benefits and risks/burdens (see the "Rating Scheme for the Strength of the Recommendations" field).

Where gaps in the evidence existed, the Panel provides guidance in the form of Clinical Principles or Expert Opinion with consensus achieved using a modified Delphi technique if differences of opinion emerged.

Rating Scheme for the Strength of the Recommendations

American Urological Association (AUA) Nomenclature Linking Statement Type to Level of Certainty, Magnitude of Benefit or Risk/Burden, and Body of Evidence Strength

	Evidence Strength A (High Certainty)	Evidence Strength B (Moderate Certainty)	Evidence Strength C (Low Certainty)
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Moderate Recommendation (Net benefit or harm moderate)	Benefits > Risks/Burdens (or vice versa) Net benefit (or net harm) is moderate Applies to most patients in most circumstances and future research is unlikely to change confidence	Benefits > Risks/Burdens (or vice versa) Net benefit (or net harm) is moderate Applies to most patients in most circumstances and future research is unlikely to change confidence	Benefits > Risks/Burdens (or vice versa) Net benefit (or net harm) appears moderate Applies to most patients in most circumstances and future research is unlikely to change confidence
Conditional Recommendation (No apparent net benefit or harm)	Benefits = Risks/Burdens Best action depends on individual patient circumstances Future research unlikely to change confidence	Benefits = Risks/Burdens Best action depends on individual patient circumstances Better evidence could change confidence	Balance between Benefits & Risks/Burdens unclear Alternative strategies may be equally reasonable Better evidence likely to change confidence
Clinical Principle	A statement about a component of clinical care that is widely agreed upon by urologists or other clinicians for which there may or may not be evidence in the medical literature		
Expert Opinion	A statement, achieved by consensus of the Panel, that is based on members' clinical training, experience, knowledge, and judgment for which there is no evidence		

Cost Analysis

A formal cost analysis was not performed and published cost-analyses were not reviewed.

Method of Guideline Validation

Peer Review

Description of Method of Guideline Validation

The American Urological Association Education and Research, Inc. (AUA) conducted a thorough peer review process. The draft guidelines document was distributed to 93 peer reviewers, 41 of which submitted comments. The Panel reviewed and discussed all submitted comments and revised the draft as needed. Once finalized, the guideline was submitted for approval to the Practice Guidelines Committee (PGC) and Science and Quality Council (S&Q). It was then submitted to the AUA and Society of

Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU) Boards of Directors for final approval. It was approved by the AUA Board of Directors in March 2017.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

For some clinical issues, there was little or no evidence from which to construct evidence-based statements. Where gaps in the evidence existed, the Panel provides guidance in the form of *Clinical Principles* or *Expert Opinions* with consensus.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

The magnitude of benefit or risk/burdens, and the Panel's judgment regarding the balance between benefits and risks/burdens are taken into account for each guideline statement. Refer to the original guideline document for a discussion of evidence of benefits for specific statements.

Potential Harms

- All surgical interventions (midurethral slings [MUS], pubovaginal slings [PVS], colposuspension) to treat stress urinary incontinence (SUI) have potential adverse outcomes, such as continued incontinence, voiding dysfunction, urinary retention, pain, and dyspareunia. Clinical outcomes appear to be worse for patients who have had prior surgery for SUI, irrespective of the approach.
- With any intervention there is a risk of continued symptoms of SUI immediately after the procedure or recurrent SUI at a later time that may require further intervention.
- Possible intra-operative risks include but are not limited to bleeding, bladder injury, and urethral injury, as well as inherent risks of anesthesia, and of the procedure itself.
- Voiding dysfunction can be seen after any type of intervention for SUI and may involve both storage and emptying symptoms. There is a risk of *de novo* storage symptoms (urgency, frequency and/or urgency urinary incontinence [UUI]) or worsening of baseline overactive bladder (OAB) symptoms for patients with mixed urinary incontinence (MUI) or SUI with urinary urgency. Depending on the symptoms, this may require one of the many options available to treat OAB or, if the symptoms are thought to be related to post-operative obstruction, may require sling incision, sling loosening, or urethrolysis.
- Obstruction resulting in urinary retention is also a potential complication and would require intermittent catheterization, indwelling Foley catheter drainage, and possible sling incision, sling loosening, or urethrolysis if this does not resolve spontaneously.
- Complaints of abdominal, pelvic, vaginal, groin, and thigh pain can be seen after sling placement. In addition to generalized pain, patients should be counseled about the risk of pain associated with sexual activity. Symptoms of dyspareunia can occur following pelvic floor reconstructive surgery.
- Risks of synthetic mesh sling placement include mesh exposure into the vagina and/or perforation into the lower urinary tract, either of which could require additional procedures for surgical removal of the involved mesh and, if necessary, repair of the lower urinary tract.
- Urinary tract infection (UTI) can occur following any intervention for SUI, and the incidence appears

to be highest in the immediate postoperative period (within three months). Patients undergoing autologous fascial sling have the additional risk of possible wound infection, seroma formation, or ventral incisional or leg hernia depending on the fascial harvest site (i.e., rectus fascia versus fascia lata, respectively), and pain at the harvesting site.
- Other complications may include erosion, extrusion, neuropathy, hematoma, seroma.

Refer to the original guideline document for additional information on complications of surgery.

Contraindications

Contraindications

- A synthetic sling should not be placed concurrently with any procedure in which the urethra is opened in proximity to the sling position. Specifically, if a concurrent anti-incontinence procedure is necessary when performing a urethral diverticulectomy, urethrovaginal fistula repair, or removal of mesh from within the urethra, a synthetic sling should not be utilized.
- Physicians should strongly consider avoiding the use of mesh in patients undergoing stress incontinence surgery who are at risk for poor wound healing.
- Physicians should not place a mesh sling if the urethra is inadvertently injured at the time of planned midurethral sling procedure.
- Physicians should not perform cystoscopy in index patients for the evaluation of stress urinary incontinence unless there is a concern for urinary tract abnormalities.

Qualifying Statements

Qualifying Statements

- While these guidelines do not necessarily establish the standard of care, the American Urological Association Education and Research, Inc. (AUA) seeks to recommend and to encourage compliance by practitioners with current best practices related to the condition being treated. As medical knowledge expands and technology advances, the guidelines will change. Today these evidence-based guidelines statements represent not absolute mandates but provisional proposals for treatment under the specific conditions described in each document. For all these reasons, the guidelines do not pre-empt physician judgment in individual cases.
- Treating physicians must take into account variations in resources, and patient tolerances, needs, and preferences. Conformance with any clinical guideline does not guarantee a successful outcome. The guideline text may include information or recommendations about certain drug uses ('off label') that are not approved by the U.S. Food and Drug Administration (FDA), or about medications or substances not subject to the FDA approval process. AUA urges strict compliance with all government regulations and protocols for prescription and use of these substances. The physician is encouraged to carefully follow all available prescribing information about indications, contraindications, precautions and warnings. These guidelines and best practice statements are not intended to provide legal advice about use and misuse of these substances.
- Although guidelines are intended to encourage best practices and potentially encompass available technologies with sufficient data as of close of the literature review, they are necessarily time-limited. Guidelines cannot include evaluation of all data on emerging technologies or management, including those that are FDA-approved, which may immediately come to represent accepted clinical practices. For this reason, the AUA does not regard technologies or management which are too new to be addressed by this guideline as necessarily experimental or investigational.
- It should be noted that some of the data included in the analysis involved techniques that are no longer commercially available for reasons not necessarily related to outcomes. Indeed, the panel

recognizes that this guideline will require continued literature review and updating as further knowledge regarding current and future options continues to develop.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Clinical Algorithm

Mobile Device Resources

Quick Reference Guides/Physician Guides

Slide Presentation

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Kobashi KC, Albo ME, Dmochowski RR, Ginsberg DA, Goldman HB, Gomelsky A, Kraus SR, Sandhu JS, Shepler T, Treadwell JR, Vasavada S, Lemack GE. Surgical treatment of female stress urinary incontinence: AUA/SUFU guideline. Linthicum (MD): American Urological Association Education and Research, Inc.; 2017 Mar. 33 p. [87 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2017 Mar

Guideline Developer(s)

American Urological Association Education and Research, Inc. - Medical Specialty Society

Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction - Professional Association

Source(s) of Funding

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Guideline Committee

Surgical Management of Female Stress Urinary Incontinence Panel

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Financial Disclosures/Conflicts of Interest

All panel members completed Conflict of Interest (COI) disclosures. Disclosures listed include both topic- and non-topic-related relationships.

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Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: American Urological Association Education and Research. Guideline for the surgical management of female stress urinary incontinence: 2009 update. Linthicum (MD): American Urological Association Education and Research, Inc.; 2009. 44 p. [31 references]

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Available from the American Urological Association Education and Research, Inc. (AUA) Web site.

Availability of Companion Documents

The following are available:

Kobashi KC, Albo ME, Dmochowski RR, Ginsberg DA, Goldman HB, Gomelsky A, Kraus SR, Sandhu JS, Shepler T, Treadwell JR, Vasavada S, Lemack GE. Surgical treatment of female stress urinary incontinence: AUA/SUFU guideline. Executive summary. Linthicum (MD): American Urological Association Education and Research, Inc.; 2017 Mar. Available from the American Urological Association Education and Research, Inc. (AUA) Web site.

Surgical treatment of female stress urinary incontinence (SUI): AUA/SUFU guideline. Slide presentation from the 2017 annual meeting. Linthicum (MD): American Urological Association Education and Research, Inc.; 2017 Mar. 19 p. Available from the AUA Web site.

The AUA Guidelines-At-A-Glance mobile app is available for download from the AUA Web site.

Patient Resources

None available

NGC Status

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